K091051

DEC - 8 2009

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

Revised December 4, 2009

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Tita-Link

Regulatory Contact / Correspondent
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NOTE: Please send all correspondence concerning this 510(k) premarket notification to the regulatory contact.

Sponsor / Manufacturer
TITA-LINK
DE Hinnisdaellaan, 2
1150 Brussels
Belgium
Contact: Dr. Hugo DeClerck
Email: hugo.declerck@skynet.be

FDA Establishment Registration Number is pending.

Trade Name:

The device trade names are:

- Bollard Miniplate Skeletal Anchorage System

Device Common, Usual, or Classification Names:

Endosseous Dental Implant

Classification

Classification of this device would fall under the responsibility of the Dental panel.

Class 2 device under the following product code / regulation:

- DZE, 21 CFR 872.3640

Predicate Device [21 CFR 807.92(a)(3)]

KLS Martin – Ortho Anchorage System – K040891

Stryker Leibinger Skeletal Anchoring System – K041651

Indications for Use [21 CFR 807.92(a)(5)]

The subject devices are intended to be placed in the mouth for use as an anchor in orthodontic procedures.

Description of the Device [21 CFR 807.92(a)(4)]

The Bollard Miniplate Skeletal Anchorage System was invented by Dr. Hugo DeClerck.

The Bollard Miniplate Skeletal Anchorage System provides a fixed anchorage point for the attachment of orthodontic appliances to facilitate orthodontic movement of teeth. Small stationary points connected to bone inside the mouth allow connection of wire, elastic, or other hardware.

The Bollard Miniplate Skeletal Anchorage System includes Commercially Pure Titanium miniplates fixed by miniscrews to the cortical bone. After insertion by the surgeon the miniplates are completely covered by soft tissue. The miniplates and miniscrews are sold sterile and are sterilized using Gamma Radiation per ISO 11137-1.

The bone anchor consists of a miniplate (M) with 2 or 3 holes, a round connecting bar (C), and a fixation unit (F) with a blocking screw (S). The miniplate is fixed to the bone by self-tapping or self-drilling screws. The fixation unit contains 2 slots with a diameter of 0.045" (1.1mm). A square connecting wire with a maximum size of 0.032x0.032" can be inserted and tightly fixed by the blocking screw.

The Bollard miniplates are also offered with a hook. The Bollard with hook is smaller than the original model and contains a tube with section 0.020"x0.020". The hook can affix directly to elastics or coil springs.

The subject devices are used with standard instrumentation for orthodontic surgery including pliers, punches, screwdrivers, burrs, and grasping or holding instruments.

Technological Characteristics [21 CFR 807.92(a)(6)]

TITA-LINK believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The subject device is composed of well characterized and biocompatible material that meets applicable standards.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Tita-Link
C/O Mr. Joseph Azary
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

DEC - 8 2009

Re: K091051
Trade/Device Name: TITA-LINK Bollard Miniplate Skeletal Anchorage System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Codes: DZE
Dated: November 20, 2009
Received: November 30, 2009

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091051

Device Name: TITA-LINK Bollard Miniplate Skeletal Anchorage System

Indications for Use:

The subject devices are intended to be placed in the mouth for use as an anchor in orthodontic procedures.

Prescription Use ___X_____ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Kevin Mulvey for HSE

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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